

**Notice of Allowability**

Application No.

09/407,182

Applicant(s)

SIEGEL, DONALD L.

Examiner

Art Unit

Timothy M. Brown

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment mailed 5/24/05 and the Telephonic Interview of 6/7/05.
2. ☒ The allowed claim(s) is/are 10-23.
3. ☒ The drawings filed on 29 September 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

***Examiner's Amendment***

An examiner's amendment to the record appears below. Authorization for this examiner's amendment was given in a telephone interview with Thomas M.

Sossong, PhD and Kathryn R. Doyle, PhD on June 7, 2005.

Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Amend claims 10, 11, 20 and 22 as follows:

10. (currently amended) A method of detecting cell agglutination, comprising providing a mixture comprising a population of cells and a population of bacteriophage expressing a first antibody on the surface of said bacteriophage, said first antibody being specific for an antigen expressed by at least a portion of the cells in said cell population, wherein said first antibody binds to said portion of said cells causing said bacteriophage to also bind to said portion of said cells, adding said mixture to a microtube containing inert particles in an amount sufficient to form a column, and a second antibody specific for said bacteriophage, wherein said second antibody binds to said bacteriophage, allowing said mixture to sediment through said column under the force of gravity, and observing the location of said portion of said cells, wherein strong agglutination of said portion of said cells is indicated by the cells being located upon or within a top layer of said inert particles and weak agglutination of said cells is indicated by the cells being located within a lower layer

Art Unit: 1648

of said inert particles and no agglutination is indicated by the cells being located at the bottom of said microtube.

11. (currently amended) A method of detecting cell agglutination, comprising providing a mixture comprising a population of cells and a population of bacteriophage expressing a first antibody on the surface of said bacteriophage, said first antibody being specific for an antigen expressed by at least a portion of the cells in said cell population, wherein said first antibody binds to said portion of said cells causing said bacteriophage to also bind to said portion of said cells, adding said mixture to a microtube containing inert particles in an amount sufficient to form a column, and a second antibody specific for said bacteriophage, wherein said second antibody binds to said bacteriophage, allowing said mixture to sediment through said column, wherein the step of sedimentation is effected by centrifugation, and observing the location of said portion of said cells, wherein strong agglutination of said portion of said cells is indicated by the cells being located upon or within a top layer of said inert particles and weak agglutination of said cells is indicated by the cells being located within a lower layer of said inert particles and no agglutination is indicated by the cells being located at the bottom of said microtube.

20. (currently amended) A method of capturing cells comprising providing a mixture comprising a population of cells and a population of bacteriophage expressing a first antibody on the surface of said bacteriophage, said first antibody being specific for an antigen expressed by at least a portion of the cells in said cell population, wherein said first antibody binds to said portion of said cells causing said bacteriophage to

Art Unit: 1648

also bind to said portion of said cells, adding said mixture to a microtube containing inert particles which have bound thereto a second antibody specific for said bacteriophage, wherein said inert particles are present in an amount sufficient to form a column, allowing said mixture to sediment through said column under force of gravity, wherein captured cells are located upon or within a top layer of said inert particles.

22. (currently amended) A method of detecting capturing of cells comprising providing a mixture comprising a population of cells and a population of bacteriophage expressing a first antibody on the surface of said bacteriophage, said first antibody being specific for an antigen expressed by at least a portion of the cells in said cell population, wherein said first antibody binds to said portion of said cells causing said bacteriophage to also bind to said portion of said cells, adding said mixture to a microtube containing inert particles which have bound thereto a second antibody specific for said bacteriophage, wherein said inert particles are present in an amount sufficient to form a column, allowing said mixture to sediment through said column under force of gravity, and observing the location of said portion of said cells, wherein capturing of said portion of said cells is indicated by the cells being located upon or within a top layer of said gel particles and the absence of capturing of said cells is indicated by the cells being located at the bottom of said microtube.

***Examiner's Comment***

European Patent Application No. 0281363 A2 by Twardzik et al. is relevant to Applicants' disclosure in that it teaches the isolation of blood platelets (see

Art Unit: 1648

Example 2). This reference however does not teach or fairly suggest (a) the use of a bacteriophage to agglutinate cells for isolation, or (2) separating agglutinated cells through the use of a column of inert particles.

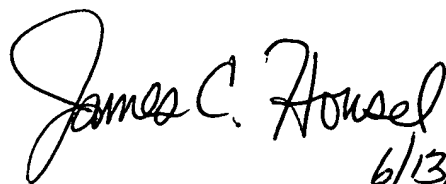
### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmb



JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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Timothy M. Brown  
Examiner  
Art Unit 1648

6/13/05

6/17/05  
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